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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/681,302	03/15/2001	Samuel F. Liprie	INE-0044-C1	9547

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EXAMINER

KEITH, JACK W

ART UNIT	PAPER NUMBER
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3641

DATE MAILED: 02/01/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/681,302

Applicant(s)

Liprie

Examiner

Jack Keith

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-- Th MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on Dec 18, 2001

2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 1-32 is/are pending in the application.

4a) Of the above, claim(s) 3 and 19 is/are withdrawn from consideration.

5) ☐ Claim(s) is/are allowed.

6) ☒ Claim(s) 1, 2, 4-18, and 20-32 is/are rejected.

7) ☐ Claim(s) is/are objected to.

8) ☐ Claims are subject to restriction and/or election requirements.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.

2. ☐ Certified copies of the priority documents have been received in Application No. _____.

3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☒ Notice of References Cited (PTO-892)

18) ☐ Interview Summary (PTO-413) Paper No(s). _____

16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

19) ☐ Notice of Informal Patent Application (PTO-152)

17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 4 & 8

20) ☐ Other:

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DETAILED ACTION

Election/Restriction

1. Applicant's election without traverse of species III, A, a (nickel/titanium alloy), b (titanium) and c (gold) in Paper No. 7 is acknowledged.
2. Claims 3 and 19 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 7.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
4. Claims 1, 2, 4-18 and 20-32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
 - a. In the claims (particularly 1, 14 and 25) it is unclear whether the housing tube is positively recited as being part of the flexible source wire. Statements about intended uses, capabilities, or structures which may result upon the performance of future acts (i.e., when bent), are not positive structural limitations and in this sense fail to comply with the requirements of the statute in failing to distinctly claim the actual invention. Note In re Collier, 158 USPQ 266.

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b. Regarding claims 5-7, 16 and 26, the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 1, 2, 4-18 and 20-32 are rejected under 35 U.S.C. 103(a) as obvious over Liprie (5,282,781) in combination with Nariciso et al (5,454,794) and Ishibe et al (5,230,348).

Liprie ('781) discloses applicant's inventive concept. A source wire for localized radiation treatment of tumors comprising: a flexible elongated *stainless steel* (12) tube/housing an outer diameter of 0.018 inches, the tube/housing further comprising a distal end (15) and proximal end (14); a flexible *stainless steel* backbone wire (17) with a distal and proximal end disposed within the tube/housing; an iridium-192 radiation source (25) provided in the tube/housing adjacent the proximal end of the flexible backbone wire, the source being two centimeters in length; and a *stainless steel* plug (27) sealing the proximal end of the tube/housing.

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Liprie ('781) further discloses that the flexible elongated tube/housing can be constructed of other materials such as titanium or *tantalum* and that the outer surface of the flexible elongated tube/housing is coated with a non-oxidizing agent (i.e., gold). Liprie ('781) also discloses a crimping method of affixing the flexible elongated tube/housing to the backbone wire. Additionally, Liprie ('781) discloses that it is well known within the art to encapsulate the radiation source in a material such as stainless steel (see column 4, lines 10+) to prevent the flaking of the radiation source and to provide such sources with radiopaque markers so as to observe the source with fluoroscopy (see column 16, lines 64+). Also note Liprie ('781) further discloses (see figure 1 and column 9, lines 19+) the tapered funnel shaping of the housing tube to facilitate entry/loading of the radiation source.

Stainless steel or *tantalum* are material equivalents for Nitinol® this is evident by Nariciso. Referring to column 3, lines 35-40 Nariciso teaches that deflecting wires can be fabricated from metals having tensile strength and memory to deflect and return to their original position such as Nitinol®, *stainless steel* or *tantalum*.

Further note that Ni-Ti alloys (i.e., Nitinol®) are well known within the medical guide wire art. This is evident by the teachings of Ishibe wherein a superelastic alloy comprising Ni (50-60% (preferably 54-57%)) and Ti (40-50% (preferably 43-46%)) provides no stress induced martensitic or martensitic reverse transformations in an elongation range of 0-5%.

In regard to the claim limitation a "a flexible backbone wire having a proximal end, said proximal end of said wire being disposed in said housing tube, and further wherein the proximal

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end of said backbone wire is rounded”, Liprie (‘781) discloses that the backbone wire (17) is crimped at location (18) with the source wire being further crimped at the same location (21) to hold the backbone wire in place. Crimping the backbone wire/source wire would indeed cause a deformation of the backbone wire material. Depending on the crimping force a bulb ^{could} ~~could~~ occur on the end of the backbone wire making it appear rounded. However, it is not apparent that Liprie (‘781) is capable of meeting applicant’s claimed intent then Ishibe (see figure 2 and column 3, lines 23+) further teaches the rounding/bulbing (7) of a core wire (2) for the purpose of preventing the core wire from puncturing the distal end of the sheath (3). Clearly, this would be applicable to Liprie (‘781) which discloses the fragility of the radioactive source. Such rounding/bulbing of the backbone wire would prevent the flaking of the radioactive source.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have replaced the stainless steel or tantalum alloy of Liprie (‘781) with the Nitinol alloy teachings of Nariciso or Ishibe, because such results are in no more than the substitution of conventionally known alloys with little or no memory retention.

Furthermore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the flexible backbone wire of (Liprie (‘781) to have included the flexibility enhancement (i.e., bulbing or rounding of the proximal end of the backbone wire) teachings of Ishibe, to gain the advantages thereof (i.e., increased flexibility, prevent puncture of the radioactive source (i.e., flaking)), because such results are in no more than the use of conventionally known flexibility techniques within the radiation source wire art.

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7. Claims 1, 2, 4-18 and 20-32 are rejected under 35 U.S.C. 103(a) as obvious over Liprie (5,282,781) in combination with Nariciso et al (5,454,794), Ishibe et al (5,230,348) and Suthanthiran et al ('896).

As discussed above the combination (Liprie ('781), Nariciso and Ishibe) discloses applicant's inventive concept; however, none of the references disclose the use of titanium (based on applicant's election of titanium as the thin-walled capsule material in Paper no. 7) encapsulating the radioactive source.

Suthanthiran (see abstract and figure 1) teaches the use of titanium encapsulation of radioactive sources in the same field of endeavor for the purpose of effectively sealing radioactive source.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified encapsulated source of the combination (Liprie ('781), Nariciso and Ishibe) to have included the material teachings of Suthanthiran as such results are in no more than the use of conventionally known encapsulation materials within the radiation source wire art.

Conclusion

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jack Keith whose telephone number is (703) 306-5752. The examiner can normally be reached on Monday through Friday from 7:00 to 4:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Carone, can be reached on (703) 306-4198. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-7687.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1113.

jwk

January 28, 2002



MICHAEL J. CARONE
SUPERVISORY PATENT EXAMINER